DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 31 1997

0104 '97 APR 10 P2:55

John Spector, C.E.O.
Caprice-Greystoke, Ltd.
1259 Activity Drive
Vista, CA 92083

Re: Docket Nos. 81N-0022/CP18 and
76N-052N/CP16

Dear Mr. Spector:

This is in response to your July 25, 1996, letter referring to a December 8, 1995, citizen petition submitted by you on behalf of Caprice-Greystoke, Ltd., requesting that the Food and Drug Administration (FDA) (1) open the administrative record to include certain studies on "Spray-U-Thin," an over-the-counter (OTC) oral liquid immediate-release appetite suppressant containing phenylpropanolamine hydrochloride (PPA); (2) ban all extended-release weight control drug products containing PPA unless certain conditions are met; (3) suspend or reprimand certain Center for Drug Evaluation and Research (CDER) officials; (4) discontinue any protocol written by the Nonprescription Drug Manufacturers Association (NDMA); (5) reject the 1986 Weintraub study; (6) conduct an investigation of Ceiba-Geigy and FDA officials named in the petition, and advise the Attorney General of the ongoing investigation and the possibility of corrupt acts; (7) accept all past petitions submitted by the petitioner; (8) provide an explanation from the Director of CDER concerning the promotions of Drs. Michael Weintraub and William Gilbertson; (9) halt publication of the OTC weight control tentative final monograph (proposed rule) and final monograph (final rule) until investigations are completed and made part of the public record; and (10) extend Category III for PPA to cough-cold medications.

Based on a fair evaluation of all facts and information before it, FDA issued a response to your citizen petition on May 17, 1996. We regret that you are unsatisfied with the agency's findings, as articulated in its response to your petition. However, under FDA regulations (21 C.F.R. 5.20(b) and 10.45(d)), the response is the Commissioner's final decision and constitutes final agency action on issues raised in the petition. Because your July 25, 1996 letter raised no new issues, FDA's May 17, 1996 response to your petition stands as the final reply to your letter.

Sincerely yours,

Jane Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

76N-052N

LET 118